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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/597,290	12/30/2008	**Robert James Nash**	2245.074	8876

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HESLIN ROTHENBERG FARLEY & MESITI PC
5 COLUMBIA CIRCLE
ALBANY, NY 12203

EXAMINER	
BASQUILL, SEAN M	
ART UNIT	**PAPER NUMBER**
1613	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/597,290	NASH ET AL.	
	Examiner	Art Unit	
	Sean Basquill	1613	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 August 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *88-107* is/are pending in the application.

4a) Of the above claim(s) *96-107* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *88-95* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *19 July 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *16 Nov 2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Claims 88-95 directed to methods of immunotherapy in the reply filed on 5 August 2010 is acknowledged.

Claims 1-87 have been cancelled by applicants amendment, and Claims 96-107 withdrawn as directed to nonelected inventions. Claims 88-95 are presented for examination.

Priority

2. Applicant's claim for the benefit of the prior-filed International application PCT/GB2005/000215 is acknowledged.

Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Great Britain on 21 January 2004. It is noted, however, that applicant has not filed a certified copy of the GB0401238.1 application as required by 35 U.S.C. 119(b).

Claim Rejections - 35 USC § 112 First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 88-95 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant

art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The description requirement of the patent statute requires a description of an actual invention, not merely an indication of a result that one might achieve if one made that invention. *See*, e.g., *In re Wilder*, 22 USPQ 369, 372-3 (Fed. Cir. 1984) (holding that a claim was not adequately described because the specification did 'little more than outline goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate'). This matter is of particular importance in the evaluation of claims drawn to a chemical genus described by the existence of either a core chemical moiety or a function which a component is to provide. It is well recognized that a description by function alone does not suffice to sufficiently describe an invention because it is only an indication of what the claimed invention does, rather than what it is. MPEP § 2163(II)(A)(3)(a), *citing Regents of the University of California v. Eli Lilly, Inc.*, 119 F.3d, 1559, 1568(Fed. Cir. 1997). An adequate written description of a chemical invention requires a precise definition, such as by structure, formula, chemical name, or physical properties. *University of Rochester v. G.D. Searle & Co.*, 358 F.3d 916, 927 (Fed. Cir. 2004). It has been held that "a generic claim may define the boundaries of a vast genus of chemical compounds, and yet the question may still remain whether the specification... demonstrates that the applicant has invented species sufficient to support a claim to a genus" with such breadth. *Ariad Pharmaceuticals, Inc. v. Eli Lilly & Co.*, 94 USPQ2D 1161, 1171 (Fed. Cir. 2010). An adequate written description requires a precise definition, such as by structure, formula, chemical name, physical properties, or other properties of species falling within the genus sufficient to distinguish the genus from other materials. *Id.*, quoting

Regents of the University of California v. Eli Lilly & Co., 119 F.3d 1559, 1568 (Fed. Cir. 1997).

However, merely drawing a fence around the outer limits of a purported genus is not an adequate substitute for describing a variety of materials constituting the genus and showing that one has invented a genus and not just a species. *Ariad*, 94 USPQ2D at 1171. 35 U.S. C. 112, first paragraph, requires a description of the invention that "clearly allow[s] persons of ordinary skill in the art to recognize that the inventor *invented* what is claimed." *Ariad* at 1172, quoting *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555 (1562-63) (Fed. Cir. 1991) (emphasis added). A sufficient disclosure is one which reasonably conveys to one having ordinary skill in the art that the inventor had possession of the claimed subject matter as of the filing date of the application in question. *Vas-Cath*, 935 F.2d at 1563. The description must reasonably describe the invention, not simply indicate a result which one might achieve if one actually made the invention. *Eli Lilly*, 119 F.3d at 1568. To properly evaluate whether an applicant has complied with the written description requirement therefore requires an analysis of whether the skilled artisan would recognize, from the description provided, the applicants were in possession of sufficient compounds representing the full breadth of diversity of the genus claimed.

Here, applicants have claimed an extraordinarily large genus of a variety of chemical compounds defined solely by the function they are to provide, specifically "alkaloids" and "toll-like receptor ligands." The size of the genera thus described are phenomenal, against which the applicants have offered evidence of having particularly described and used only 15 compounds falling within the genus of alkaloids (Pages 48-50 of the specification as originally filed) and two toll-like receptor ligands (lipopolysaccharides and monophosphoryl lipids (Pg. 31, lines 36-37) as currently claimed. The particularly described compounds only represent a minute fraction of

the various genera which the applicants have claimed, and in no way either represent the breadth of variable moieties which applicants have claimed, nor permit the skilled artisan to recognize that such claim breadth was actually in the applicants possession as of the time of filing the instant application.

4. Claims 88-93 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the use of alkaloids which induce the production of IL-2 in certain types of immunotherapy, does not reasonably provide enablement for the use of any alkaloid to induce immunotherapy generally. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

To be enabling, the specification of the patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation. *In re Wright*, 999 F.2d 1557, 1561 (Fed. Cir. 1993). Explaining what is meant by "undue experimentation," the Federal Circuit has stated:

> The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed to enable the determination of how to practice a desired embodiment of the claimed invention. *PPG v. Guardian*, 75 F.3d 1558, 1564 (Fed. Cir. 1996).[1]

The factors that may be considered in determining whether a disclosure would require undue experimentation are set forth by *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404

[1] As pointed out by the court in *In re Angstadt*, 537 F.2d 498 at 504 (CCPA 1976), the key word is "undue", not "experimentation".

where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

1) the quantity of experimentation necessary,
2) the amount of direction or guidance provided,
3) the presence or absence of working examples,
4) the nature of the invention,
5) the state of the prior art,
6) the relative skill of those in the art,
7) the predictability of the art, and
8) the breadth of the claims.

These factors are always applied against the background understanding that scope of enablement varies inversely with the degree of unpredictability involved. *In re Fisher*, 57 CCPA 1099, 1108, 427 F.2d 833, 839, 166 USPQ 18, 24 (1970). Keeping that in mind, the *Wands* factors are relevant to the instant fact situation for the following reasons:

a. The nature of the invention, state and predictability of the art, and relative skill level

The invention relates to methods of performing immunotherapy by administration of the combination of an alkaloid and a toll-like receptor ligand. The relative skill of those in the art is high, requiring extensive training in medicine, pharmacology, biochemistry, molecular biology and the like. That factor is outweighed, however, by the unpredictable nature of the art. As illustrative of the state of the art, the examiner directs the applicants to their own specification, which indicates that only those alkaloids which are capable of inducing an up regulation of IL-2 production can potentially be used as immunotherapy adjuvants. (Specification pg. 23, lines 10-11). In addition, the use of Toll-like receptors in immunomodulation is highly unpredictable, as of the time of the instant invention, while multiple toll-like receptors have been identified, the

cellular response to various TLR ligands was known to be highly variable. Caetano Reis e Sousa, *Toll-Like Receptors and Dendritic Cells: For Whom the Bug Tolls*, 16 SEM. IMMUN. 27, 28 (23-Jan-2004). Indeed, at the time of the instant invention, TLR signaling pathways differ from one another, eliciting different biological responses depending upon which is activated, but additionally indicating that it is possible that TLR ligands would, in addition to a decent body of knowledge supporting the role of TLR in inducing bacterial immunity, in a similar manner induce immunity against viral antigens, but merely indicating the mere possibility of it's application in the treatment of additional diseases and disorders. Shizuo Akira, *Mammalian Toll-Like Receptors*, 15 CURR. OPIN. IMMUNOL. 5, 8, 9 (February 2003).

b. The breadth of the claims

The claims are extraordinarily broad, indicating that any compound capable of classification as an alkaloid can be used successfully to improve any type of immunotherapy directed toward the treatment, prevention, or amelioration of any disease, disorder, or disruption of any bodily system which would involve, depend from, or result in an immune response when co-administered with a toll-like receptor ligand. It is important to note that the instant claims are dissociated from any disease, disorder, or disruption associated with any bodily system or agglomeration of systems.

c. The amount of direction or guidance provided and the presence or absence of working examples

The specification provides no direction or guidance for practicing the claimed invention in its "full scope." No reasonably specific guidance is provided concerning useful therapeutic protocols for immunotherapy, other than the apparent ability of the administration of certain

polyhydroxylated pyrrolizidine alkaloids in combination with toll-like receptor ligands to effect the inhibition of certain enzymes or induce the production of certain cytokines related to infectious disease, inflammatory responses, and some hyperproliferative disorders. Particular attention is to be directed to the specification at pages 48-50 of the instant specification. Here, applicants have particularly listed 15 alkaloid compounds, as well as provided data concerning their ability in vitro to induce the production of IL-2. Applicants have indicated that only 9 of the 15 compounds, in controlled laboratory conditions, are capable of being classified as the "activating alkaloids" which induce the production of IL-2 as required by the disclosure. The working examples therefore only support the possible enablement of a limited range of the broad spectrum of immunotherapy encompassed by the instant Claims by the use of a very narrow selection of alkaloid compounds in combination with an even narrower set of TLR ligands.

d. The quantity of experimentation necessary

Because of the known unpredictability of the art, and in the absence of experimental evidence, no one skilled in the art would accept the assertion that any alkaloid and any toll-like receptor ligand could be predictably used in immunotherapy as inferred by the claim and contemplated by the specification. Accordingly, the instant claims do not comply with the enablement requirement of §112, since to practice the claimed invention in its "full scope" a person of ordinary skill in the art would have to engage in undue experimentation, with no reasonable expectation of success.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 88-95 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shizuo Akira, *Mammalian Toll-Like Receptors*, 15 CURR. OPIN. IMMUNOL. 5, 8, 9 (February 2003) (hereinafter "Akira"), in view of Ruain Xu, *et al*, *Molecular Therapeutics of HBV*, 3 CURR. GENE THERAPY 341 (2003) (hereinafter "Xu"), Alison Watson, *et al*, *Polyhydroxylated Alkaloids - Natural Occurrence and Therapeutic Applications*, 56 PHYTOCHEM. 265 (2001) (hereinafter "Watson"), as evidenced by Andrew Bell, *et al*, *Synthesis of Casuarines [Pentahydroxylated Pyrrolizidines] by Sodium Hydrogen Telluride-Induced Cyclisations of Azidodimesylates*, 38 TET. LET. 5869 (1997) (hereinafter 'Bell").

As a threshold matter, the examiner notes that the instant invention relates to a method of providing immunotherapy by the administration of a combination of compounds, specifically any toll-like receptor ligand in combination with any alkaloid. So far as positively recited method steps are concerned, the only method the instant claims describe is the administration of both a

toll-like receptor ligand and an alkaloid to a patient. The method is not particularly limited in terms of disease or other descriptor of patient population, nor in terms of the insult to which the immune system is to be conditioned against. The language presented in Claim 89 neither particularly addresses these issues, nor recites affirmative additional steps to be taken, nor provides limitation as to the identity of the agents which are to be used in providing the therapy so claimed. As such, the examiner has determined that the language of Claim 89 recites simply the results the applicants intend to achieve by the performance of the actual method steps which have been particularly and positively recited. As such, in terms of the examination of the instant claims, they are of no import in terms of defining the invention so claimed.

Akira discussed the biochemical role played by toll-like receptor (hereinafter "TLR") ligands in the induction of immune responses, Particularly noting that lipopolysaccharides and lipoproteins in particular induce immunostimulatory responses. (Pg. 5-6). Akira indicates that the immunostimulation proceeds by the up regulation of a variety of cytokines and interleukins known to promote the development of immunity. (Pg. 8-9). Akira indicates that a variety of TLRs are involved in the induction of immunity in response to lipopolysaccharides and lipoproteins presented by bacteria, mycobacteria, and fungi, and further indicate that some TLRs may be involved in the production of immune responses to viral antigens. (Pg.9). This indicates that exposing immune systems to certain bacterial, fungal, and viral TLR ligands would induce an immune response by promoting the production of cytokines and other cellular signaling media, the core of immunotherapy in relation to those antigens.

Akira does not however, discuss or provide a rational for combining immunotherapy directed to bacterial, fungal, or viral infections by administering a combination of a TLR ligand such as a lipopolysaccharide and a polyhydroxylated alkaloid such as Casuarine.

Xu, however, discusses the implications of immunotherapy, particularly in the context of HBV vaccination. (Abs.). Xu describes a variety of approaches to promoting improved immunotherapy, including not only direct antiviral strategies, but also the modulation of the immune system of the subject to be treated. (Pg. 345). In particular, Xu notes that glucosidase inhibitors, which interfere with the ability of cells to properly form enveloping membranes, have demonstrated an ability to act as antiviral agents by preventing the proper envelopment of viral genetic material. (Id.). Additionally, Xu indicates to avoid the sometimes severe side effects associated with systemic administration of immunomodulatory cytokines, means of endogenous production or localized administration thereof would provide greater benefit in developing acquired immunity. (Pg. 345-46).

Because Akira discloses means of inducing endogenous immune responses including increasing the production of immunomodulatory cytokines by the administration of TLR ligands such as lipopolysaccharides, and Xu indicates that such an immunomodulatory induction may successfully be coupled with other therapeutic means, such as the administration of a glucosidase inhibitor, the skilled artisan at the time of the instant invention would be guided to the combination of immunomodulation and glucosidase inhibition as a successful means of treating, at least, viral infection.

Against this background, Watson indicates that a variety of polyhydroxylated alkaloids, including casuarine and swainsonine, act as potent, reversible, and competitive glycosidase

inhibitors, with casuarine in particular, falling within the genus described in Claims 94 and 95, noted as a inhibitor of a variety of a-glucosidases. (Pg. 275-76, 278). Watson additionally indicates that owing to this activity, polyhydroxylated alkaloids such as casuarine would find utility as immune stimulants, anti-viral agents, and general anti-infective agents owing to the fact that inhibition of glucosidase is known to inhibit the proper formation of cell walls or viral envelopes. (Pg. 283, 84, 86, 87). Indeed, Bell, et al, echo the findings of Watson vis-à-vis casuarine's activity as an inhibitor of glycosidases and glucosidase in particular.

The art then advocates, in the promotion of innate immune responses to a variety of antigens, the combination of immune stimulation and chemotherapy, and in particular the induction of localized production of immunostimulant cytokines and chemotherapy via a-glucosidase inhibition. The art recognizes toll-like receptor ligands such as lipopolysaccharides are powerful immunostimulants and promoters of immune cytokine production, and also that polyhydroxylated alkaloid compounds such as casuarine are powerful inhibitors of a-glucosidase among other glycosidases. Furthermore, in addition to acting to inhibit glucosidases, polyhydroxylated alkaloids are known by the skilled artisan as of the time of the instant invention to provide benefit in the treatment of viral and other infective agents, as well as generally acting as immunostimulants. On the basis of this knowledge, then, the skilled artisan would have the motivation to induce an improved immune response to a variety of infective agents such as bacteria, mycobacteria, fungi and viruses by the co-administration of a toll-like receptor ligand such as a lipopolysaccharide and a polyhydroxylated alkaloid such as causarine.

Double Patenting

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 88-95 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 43-60, 61, and 62 of copending Application No. 10/597,296 in view of Akira as described above. The '296 application claims methods of polarizing an immune response by administering a combination of an antigen and an alkaloid such as the casuarines of the instant claims, but does not indicate a toll-like receptor ligand can be administered. However, by the teaching of Akira, TLR ligands such as lipopolysaccharides are well-known as antigens suitable for promoting an immune response in the development of innate immunity, and therefore would have been known as a suitable immune polarizing antigen to the skilled artisan at the time of the instant invention.

This is a provisional obviousness-type double patenting rejection.

8. Claims 88-95 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 64-74 of copending Application No. 10/543,014 in view of Akira as described above. The '014 application claims methods of treating a disease such as a viral or bacterial infection by administering at least an alkaloid such as the casuarines of the instant claims, but does not indicate a toll-like receptor ligand can be administered. However, by the teaching of Akira, TLR ligands such as lipopolysaccharides are well-known as antigens suitable for promoting an immune response in the development of innate immunity to viruses and bacteria, and therefore would have been known as a suitable means of treating such diseases by the skilled artisan at the time of the instant invention.

This is a provisional obviousness-type double patenting rejection.

Conclusion

No Claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean Basquill whose telephone number is (571) 270-5862. The examiner can normally be reached on Monday through Thursday, between 8AM and 6PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Kwon can be reached on (571) 272-0581. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sean Basquill/
Examiner, Art Unit 1613

/Jeffrey S. Lundgren/
Primary Examiner, Art Unit 1639